In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 16-499V
(Filed: March 9, 2017)

JULIAN HENLEY,	*	Not to be Published
Petitioner,	*	Finding of Fact; Onset;
v.	*	Pemphigus Vulgaris;
	*	Hepatitis B Vaccine.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Colleen Hartley, U.S. Department of Justice, Washington, D.C., for respondent.

FACTUAL RULING[1]

Roth, Special Master:

On April 22, 2016, Dr. Julian Henley ("Dr. Henley" or "petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] ("Vaccine Act" or "the Program"). Petitioner alleges that the hepatitis B vaccination that he received on April 3, 2015 caused him to develop painful lesions. Thereafter, petitioner was diagnosed with pemphigus vulgaris. Petition, ECF No. 1, at 1-2.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, I intend to post this ruling on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted ruling. If, upon review, I agree that the identified material fits within the requirements of that provision, I will delete such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Respondent submits that the record raises both onset and causation issues. Regarding onset, the respondent submits that the petition "alleges that the injury occurred 'after the April 3, 2015 hepatitis B vaccination' (Pet. at ¶4), but the petition fails to provide more specific timing. Moreover, the medical records show the earliest visit for any related treatment at more than three months after the vaccination, beyond a reasonable onset period for a vaccine association." Resp. Status Report filed August 15, 2016, ECF No. 15 at 1-2. Respondent therefore requested an onset hearing.

An onset hearing was conducted on November 30, 2016. Dr. Henley testified. *See* Transcript ("Tr."), ECF No. 26, at 4-85. This ruling is intended to clarify the onset of Dr. Henley's injuries.

Having carefully considered the medical records, affidavits and testimony of Dr. Henley, I find Dr. Henley to be a credible witness. Specific factual findings are set forth in detail below. In summary, I find that Dr. Henley began suffering from symptoms of pemphigus vulgaris in May of 2016, or within 4 weeks after receipt of his hepatitis B vaccination.

I. Procedural History

The petition was filed on April 22, 2016. ECF No. 1. On May 5, 2016, petitioner filed his medical records as Petitioner's Exhibits ("Pet. Ex.") 1-5. ECF No. 7. A Statement of Completion was filed on May 10, 2016. ECF No. 8. Petitioner filed a motion to strike his Statement of Completion for improper filing on May 11, 2016, which was granted by a non-PDF Order; a Statement of Completion was re-filed on May 11, 2016. ECF Nos. 9, 10.

A status conference was held on June 2, 2016. The lack of medical records until several months after the hepatitis B vaccination was discussed. Order, issued Jun. 3, 2016, ECF No. 11. Petitioner's counsel stated that, because the petitioner is a physician, much of his care came from consulting colleagues, and there are no records for those consultations. *Id*. Since petitioner had yet to file an affidavit, he was ordered to file an affidavit detailing his injuries and explaining why he did not seek medical treatment until August of 2015. *Id*.

Petitioner filed his affidavit on June 15, 2016. Pet. Ex. 6, ECF No. 12. Thereafter, additional medical records were filed on July 7, 2016. Pet. Ex. 7 and 8, ECF No. 13. A Statement of Completion was filed on August 9, 2016. Statement of Completion, ECF No. 14.

On August 30, 2016, respondent filed a Status Report ("Res. S.R.") submitting that there were onset and causation issues. Res. S.R., ECF No. 15, at 1. Respondent requested that an onset hearing be held and a ruling issued before this matter could be evaluated for purposes of settlement or the need to engage experts on causation. *Id.* at 2. The deadline for respondent's Rule 4(c) Report was suspended. *Id*.

A status conference was held on October 6, 2016. During the conference, petitioner was asked to file a verbatim transcription of petitioner's dental records, because the records were illegible. Order, issued Oct. 6, 2016, ECF No. 17. The parties discussed the onset issue and petitioner was ordered to file a status report regarding his availability for an onset hearing. *Id.*

Petitioner filed a status report ("Pet. S.R.") on October 21, 2016, stating he was available for an onset hearing between November 29, 2016 and December 2, 2016. Pet. S.R., ECF No. 18. An onset hearing was set for November 30, 2016. Pre-Hearing Order, issued Oct. 24, 2016, ECF No. 19. Petitioner filed additional medical records on November 2 and 21, 2016 as Pet. Ex. 9 and 10, respectively. ECF Nos. 20, 22. A prehearing status conference was held on November 21, 2016. Order, issued Nov. 21, 2016, ECF No. 21.

An onset hearing was held on November 30, 2016. A post-hearing order was issued for missing pages of Pet. Ex. 2 to be filed by January 17, 2017, and affidavits and documentation to be filed by January 27, 2017. That order was stricken and refiled the same day. ECF Nos. 23-24. Affidavits from petitioner's physician/colleagues, Dr. Massey and Dr. Blomstedt, were filed on December 20, 2016. Pet. Ex. 11-12, ECF No. 27. Petitioner filed additional medical records on January 19, 2017. Pet. Ex. 13, ECF No. 31.

The matter is now ripe for adjudication.

II. Legal Standards Regarding Fact Finding

Petitioners bear the burden of establishing their claims by a preponderance of the evidence. § 300aa-13(a)(1). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues, such as the timing of onset of petitioner's alleged injury, begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa-11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information about a patient's health problems). *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010).

There are situations in which compelling oral testimony may be more persuasive than written records—for instance in cases where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health &Human Servs.*, 69 Fed. Cl. 775, 779 (2006)("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.,* 991 F.2d. 1570, 1575 (Fed. Cir. 1993).

When witness testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *85 (Fed. Cl. Spec. Mstr. June 30, 1998). In making

a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns by Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993).

III. The Factual Record

The hearing in this matter focused on the events and medical treatment shortly before and after petitioner's receipt of his third hepatitis B vaccine on April 3, 2015, and the onset of, or first manifestations of, his injuries. Therefore, the facts presented below will address only those which are directly related to the onset of petitioner's injuries. This decision should not be interpreted to mean that the remainder of the facts, medical history, affidavits and testimony are not important or are not being considered. Only the facts and evidence directly related to onset are being addressed in this Decision.

A. Summary of the Relevant Medical History

To preface the relevant medical history, and as more specifically set forth below, in 2012, petitioner, a physician, moved from the East Coast to the Midwest to join Regional West Medical Center ("RWMC"). Tr. 5.23 to 6.1. Following a work-required physical, petitioner was advised that his blood work failed to show antibodies to hepatitis B and he would be required to take the vaccine. Tr. 5.12 to 5.20. Thereafter, petitioner received three hepatitis B vaccinations on the following dates: December 6, 2012, October 28, 2014, and April 3, 2015. Pet. Ex. 5 at 1.

On February 19, 2013, petitioner presented to Platte Valley Dental Group ("Dental") in Scottsbluff, Nebraska, for a dental cleaning. Pet. Ex. 9 at 1. He was noted to have heavy gingival bleeding. The cleaning was completed with a hand instrument only. *Id*. It was recommended that he return in 6 months. *Id*.

On July 8, 2014, almost seventeen months later, petitioner returned to Dental with a broken tooth. Pet. Ex. 9 at 1. Upon examination, it was noted that both tooth #29 and #31 needed treatment. *Id.* Petitioner agreed to the treatment of both teeth. *Id*.

Petitioner returned to Dental on August 6, 2014, for completion of the crowns necessary for teeth #29 and #31. Pet. Ex. 9 at 1. A dental cleaning was done on that date. *Id*. Treatment for gum inflammation was discussed. *Id*. It was recommended that petitioner return in three months; however, petitioner stated that he could do only a six-month return due to his schedule. *Id*.

Petitioner underwent blood testing for work on September 4, 2014 at RWMC. The results again indicated that petitioner was not immune to hepatitis B. Pet. Ex. 1 at 1. He was administered a second hepatitis B vaccination on October 28, 2014. Pet. Ex. 5 at 1. Petitioner received a third hepatitis B vaccination on April 3, 2015. *Id*.

On April 14, 2015, established care with a primary care physician ("PCP"). Pet. Ex. 2 at 1. He was noted to be a 67-year-old physician with prostate issues and swelling of the legs with some pedal edema over the past 6 or 7 years. *Id.* Stress test and an echocardiogram done several years before were noted to be normal; he had an appendectomy when he was young, followed by

hepatitis resulting from a penicillin injection.[3] *Id*. at 1, 3. He had previously been diagnosed with hypertension, and was prescribed Lisinopril, but developed angioedema and discontinued the medication. *Id*. at 1. He was following a paleo diet and trying to restrict his salt intake. *Id*. Petitioner complained of edema in his legs, right worse than left with no other symptoms. *Id*. Minor pitting edema in his legs was noted on examination. *Id*. at 2. The assessment on that day was enlarged prostate, venous insufficiency, leg edema, and elevated blood pressure. A family history of diabetes, lung cancer, colon cancer, gastrointestinal cancer, and hypertension was noted. *Id*. at 3. Petitioner was prescribed Cialis for his prostate and vascular support stockings. *Id*.

On May 15, 2015, a hepatitis B surface test was positive for immunity to hepatitis B. Pet. Ex. 1 at 9.

On June 23, 2015, petitioner presented to Dental complaining of tender gums with bleeding on the top and bottom of the right side of his mouth. Pet. Ex. 9 at 2. Upon examination, it was noted that petitioner had severely red tissue with 5-6 mm pocketing. *Id*. It was recommended that petitioner consult with a periodontist, return to Dental in three months, and rinse with Peridex regularly, none of which petitioner was interested in. *Id*.

Petitioner had an emergency visit to Dental on June 28, 2015, due to severe pain and an abscess on tooth #29. Pet. Ex. 9 at 2. The tooth was treated and petitioner was prescribed an oral antibiotic and Peridex rinse. *Id*. Petitioner returned to Dental on July 17, 2015, for final treatment of tooth #29. No complaints were noted. Pet. Ex. 9 at 2.

On August 17, 2015, petitioner presented to the Eye Center of Northern Colorado ("Eye Center") complaining of redness and irritation of his right eye. Pet. Ex. 7 at 9. It was noted that petitioner had tried multiple types of eye drops without improvement. *Id*. Petitioner's eye was noted to be normal with a clogged Meibomian gland[4] and a hordeolum (stye);[5] hot compresses and antibiotic drops (ciprofloxacin) were prescribed. *Id*. at 11.

On August 24, 2015, petitioner presented to Dr. John Blomstedt at RWMC complaining of a chronic pruritic scalp rash which he was scratching constantly, and lesions on his right lower eye lid and the right side of his nose. He had been trying topical steroids, antifungals and topical antibiotics without improvement. Petitioner requested biopsies. Pet. Ex. 3 at 1. Biopsies performed

[3] Petitioner testified to the sanitary conditions in Poland, where he was born and raised, and how he contracted hepatitis from needles that were reused at that time. Tr. 42.8 to 43.6.

[4] The Meibomian glands are sebaceous glands in the eyelids that secrete oils onto the surface of the eye to help keep tears from evaporating too quickly. "Dry eyes," MAYO CLINIC, mayoclinic.org.

[5] Hordeolum is a "stye," or "suppurative infection of a marginal gland of the eyelid." STEDMAN'S POCKET MEDICAL DICTIONARY (1st ed. 1987) at 346, hereinafter "Stedman's." It may present externally, as an "inflammation of the sebaceous gland of an eyelash," or internally, as an "acute purulent infection of a Meibomian gland." *Id*.

on the vertex of his scalp and right nasolabial fold were positive for pemphigus vulgaris.[6] *Id*. at 1-2-4.

On August 27, 2015, petitioner returned to the Eye Center. The lesion on his lower eyelid had not improved and continued to be bothersome, despite the recommended warm compresses and antibiotic drops. Pet. Ex. 7 at 13. There was concern that day due to the appearance of the lesion. *Id*. at 15. A biopsy of the right lower eyelid showed extensive epidermal acantholytic dyskeratosis[7] raising concern for an acantholytic disorder, such as pemphigus or Hailey-Halley disease. *Id*. at 1, 17.

Laboratory work performed on September 16, 2015 resulted in a finding of very high serum levels for both desmoglein 1 and 3.[8] Pet. Ex. 1 at 13. Additional laboratory results from September 17, 2015 indicated that petitioner had normal levels of G6PD.[9] *Id*. at 10.

On September 24, 2015, petitioner presented to the dermatology department at the University of Colorado ("dermatology") "for evaluation of pruritic and painful rash of 2 months duration involving the scalp, face and chest. Lesions are crusted over. Rash is worsening over time." Pet. Ex. 4 at 3. It was noted that petitioner had used topical steroids, antifungals, and a Medrol dose pack and Dapsone without improvement. *Id*. It was also noted that skin biopsies performed at an outside clinic revealed extensive acantholysis with dyskeratosis consistent with

---

[6] Pemphigus vulgaris is a relapsing autoimmune disease characterized "by blisters and erosions on the skin and mucous membranes, most commonly inside the mouth." Other areas that can be affected include the conjunctiva, esophagus, and genitals. Vanessa Ngan, "Pemphigus Vulgaris," DERMNET NEW ZEALAND, dermnetnz.org, last updated 2003.

[7] "Dyskeratosis" is a histological term referring to abnormal keratinocytes (skin cells). "Acantholysis" is a histological term referring to "floating" skin cells that have lost normal cell-to-cell connections. "Acantholytic dyskeratosis" is the separation of keratinocytes within the epidermis due to the loss of adhesion between cells. With pemphigus foliaceus, this separation occurs just below the granular (middle) layer of the epidermis; however, in pemphigus vulgaris, the separation occurs in the basal (deepest) layer of the epidermis. Anthony Yung, "Glossary of dermatopathological terms," DERMNET NEW ZEALAND, dermnetnz.org, last updated June 2016.

[8] Desmoglein is "any of a family of cadherins found in desmosomes; they are the target of autoantibodies in pemphigus foliaceus and pemphigus vulgaris." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) at 507, hereinafter "Dorland's." Desmosome is "a site of adhesion between two cells, consisting of a dense plate separated from a similar structure in the other cell by a thin layer of extracellular material." Stedman's at 198. Pemphigus vulgaris is indicated by IgG and desmoglein3; pemphigus foliaceus is indicated by IgG and desmoglein1.

[9] G6PD stands for "glucose-6-phosphate dehydrogenase." It is an enzyme which helps the body process carbohydrates; it also protects red blood cells from oxidative stress. G6PD deficiency can result in hemolysis, or destruction of red blood cells, and hemolytic anemia. Hemolytic episodes can be triggered by certain medications, foods, infections, or severe stress. "G6PD Deficiency," KidsHealth.org, The Nemours Foundation.

pemphigus foliaceus,[10] and that labs sent to the Mayo Clinic were positive for desmoglein 1 and 3. *Id*. The assessment was "[l]ikely Pemphigus foliaceus…" *Id*. at 3. Petitioner was prescribed doxycycline, two infusions of rituximab, and continued use of Dapsone. *Id*. at 3, 6.

A shave biopsy performed that day on petitioner's left shoulder was consistent with a type of pemphigus, but did not clearly distinguish pemphigus vulgaris from pemphigus foliaceus. Pet. Ex. 4 at 4, 16.

Petitioner returned to dermatology on October 22, 2015. It was noted that the pemphigus was more consistent with vulgaris due to oral involvement and [desmoglein 3] positivity. It was the physician's opinion that the suspected trigger of the pemphigus was the hepatitis B vaccination series given the time course. Pet. Ex. 4 at 22. It was further noted, "Since his last visit in 9/2015, patient has noted progression of disease with more erosions on the upper trunk and scalp, persistent enlargement of the periorbital erosions and onset of erosions in the mouth along with buccal and lingual mucosae." *Id.* The petitioner "is somewhat resistant to higher doses of prednisone as he is currently operating and is concerned about mood changes." *Id*. at 23. "Symptoms started with erythema around a seborrheic keratosis on his upper chest following the second round of HBV series, but resolved within a few weeks. After receiving the third round in 7/2015, he noted diffuse onset of erosions on the scalp, face, and chest.[11] He was previously treated with Doxycycline, Dapsone and systemic antifungals. He was initially diagnosed with pemphigus foliaceus." *Id*. On that date, petitioner was noted to have scattered erythematous crusted erosive macules and patches mostly on his upper trunk, right periorbital area, scalp, lateral neck, abdomen, and left medial orbital rim. *Id*. at 24. Erosions were also noted on the right posterior buccal mucosa and, to a lesser extent, the lingual and left buccal mucosa. *Id*.

That same day, Dr. Norris, petitioner's dermatologist, wrote a letter stating that Dr. Henley was under his care for pemphigus vulgaris "suspected to be precipitated from hepatitis B vaccination." Pet. Ex. 4 at 30. The letter further stated that petitioner was advised to remain at home for approximately one month until reevaluation, at which time further time off would be determined. *Id*.

Petitioner returned to dermatology on November 25, 2015 where it was again noted that he had "pemphigus vulgaris with oral involvement and Dsg3 positivity, suspected trigger likely HBV vaccination series given time course." Pet. Ex. 4 at 35. Since his last appointment on October 22, petitioner had been on an increased dose of prednisone (60mg) and he had received the second of

[10] Pemphigus foliaceus is "a generally chronic form of [pemphigus] in which extensive exfoliative dermatitis, with no perceptible blistering, may be present in addition to the bullae." Stedman's at 561. It is "a superficial, mild, chronic form of pemphigus, usually occurring in the fourth and fifth decades of life, characterized by small flaccid bullae that rupture and crust, as well as localized or generalized exfoliation." Dorland's at 1425.

[11] At hearing, petitioner testified that the record incorrectly states the date of his third hepatitis B vaccination as 7/2015. Other records reflect that petitioner received the third hepatitis B vaccine on April 3, 2015. Pet. Ex. 5 at 1. Petitioner testified that, when asked how long ago he had received the third hepatitis B shot, he had stated that it was several months ago or a few months ago. Tr. 38.25 to 39.18.

two Rituximab infusions. *Id*. Petitioner's skin, eye, and oral lesions had improved. *Id*. Petitioner had self-tapered down to 40 mg of prednisone three days prior, and was tolerating it well. *Id*. The plan was to taper the prednisone and start a steroid sparing agent. *Id.* He was prescribed CellCept, and instructed to continue using "dexamethasone swish & swallow, Silvadene, and topical steroids." *Id.* Petitioner was advised that he could return to work in January as long as the skin lesions had healed. *Id.*

Petitioner returned to the dermatologist on December 23, 2015 at which time his immunosuppression was discussed in light of his profession as a surgeon in an acute care setting where he is exposed to MRSA, CMV, and other infections. Pet. Ex. 4 at 51. Though he had no new lesions, he had some disruption of the skin barrier when the skin was stretched. *Id.* at 52. His right eye was improved; there was only a "single improving lesion" in his mouth. *Id.* Petitioner wanted to return to work but had developed tremors in his hands as a side effect of the high dose steroids, which would keep him from doing surgery. *Id.*

The remainder of the medical records relate to petitioner's ongoing treatment and current medical status and are unnecessary for purposes of this onset decision.

B. Affidavits

i. Affidavit of Dr. Henley

Petitioner submitted an Affidavit on June 15, 2016. *See generally*, Pet. Ex. 6. Petitioner stated that he received hepatitis B vaccines on December 6, 2012, October 28, 2014, and April 3, 2015 at RWMC. Pet. Ex. 6 at 1.

Petitioner stated that if he had a reaction after the first vaccine, it was minor and went unnoticed. He recalled that after the second vaccine on October 28, 2014, he developed a rash on his chest which resolved on its own within weeks. *Id*.

Petitioner stated that when he was told that he had failed to develop antibodies after the second customary hepatitis B vaccine, he argued against having a third vaccine, but was told it was required. He received the third vaccine on April 3, 2015. *Id.*

Petitioner stated that within a week or two of receiving the third hepatitis B vaccine, he developed bleeding from his gums when he brushed his teeth and had several nose bleeds. *Id*. He assumed the gum bleeding was due to gingivitis and the need for a dental cleaning. *Id*. Contemporaneously with the gum bleeding and discomfort, he noted non-tender skin lesions on his scalp in the area of his surgical headlamp which he attributed to "contact irritation etiology." *Id.* Petitioner also noted that he had a concurrent stye on his right lower eyelid and a pimple-like lesion next to the right side of his nose. *Id*. at 1-2.

Petitioner stated that the dental cleaning failed to resolve the dental issues. He then developed an abscess, for which he was given antibiotics and ultimately had an emergency root canal. *Id*. at 2. Petitioner did not connect the dental issue with an autoimmune reaction. He also stated that the painful dental condition distracted him from doing anything about the skin lesions,

which were not painful at that time. *Id*. He noted that neither the stye nor the skin lesions responded to the antibiotics he took for the dental issue. *Id*.

Petitioner stated that he went to an ophthalmologist for the stye on his right eye and was told to put hot compresses on it. When that did not work, he was sent to an eyelid specialist who performed a biopsy on the stye. He also formally saw his colleague, Dr. Blomstedt, who did biopsies of the lesions on his head and nose; all of the biopsies came back as suspicious for "pemphigoid autoimmune process." *Id*.

In looking back, petitioner realized that the scalp lesions, eye lesion, and gum issues were all concurrent, and "[i]n retrospect…are recognized as early manifestations of [the] pemphigus autoimmune reaction." *Id*.

Petitioner qualified that his symptoms began "within a week or two" of receiving the third hepatitis B vaccine; the lesions were slowly evolving and not painful at the beginning. He stated that, because making appointments with specialists takes time, "there was a natural gap between the vaccination and the formal diagnosis of autoimmune pemphigus." *Id*. His insistence on biopsies accelerated the diagnosis. *Id*.

ii. Affidavit of Dr. John Blomstedt.

After the hearing in this matter, Dr. Blomstedt submitted an affidavit dated December 5, 2016, in which he stated that he works with petitioner at RWMC in Scottsbluff, Nebraska. Pet. Ex. 11 at 1. Dr. Blomstedt confirmed that in August of 2015, he performed biopsies on petitioner. *Id*. Dr. Blomstedt recalled petitioner asking him to look at the rash on his scalp, and believed that was in June of 2015. *Id*.

iii. Affidavit of James Massey, M.D.

After the hearing, Dr. Massey submitted an affidavit dated December 16, 2016. *See generally*, Pet. Ex. 12. Dr. Massey affirmed that he worked with petitioner at RWMC. Pet. Ex. 12 at 1. Dr. Massey affirmed that approximately two years ago, Dr. Henley asked him to look at an area on his shoulder that he was concerned about, as it previously had been cancerous. Dr. Massey affirmed that a biopsy was considered but never done. *Id*.

C. Testimony at Hearing

Petitioner was the only witness who testified at hearing. He is a 67 year old physician who specializes in head and neck surgery, including trauma and cancer to the head and neck. Tr. 5.5 to 5.11. He sees patients in a clinical setting for otolaryngology issues as well. Tr. 5.8 to 5.9.

Petitioner explained that his work schedule requires him to alternate weeks between Scottsbluff, Nebraska and Colorado, where he divides his time between Fort Collins and Greeley. Tr. 67.18 to 67.22. The trauma aspect of his job requires him to be on call at night in both Nebraska and Colorado when he is in each of those states. Tr. 68.1 to 68.4.

He typically sees patients in Scottsbluff during the day and is on call on nights and weekends for trauma. He then drives back to Colorado on Monday morning or Sunday night and sees patients and is on call for trauma there. Scottsbluff is divided between himself and Dr. Massey, who practices in the same specialty. When petitioner is in Scottsbluff, Dr. Massey is in Mississippi and when Dr. Massey is in Scottsbluff, petitioner is in Colorado. Tr. 69.10 to 69.24. Petitioner is on call seven nights a week in both places. Tr. 70.1 to 70.19.

Petitioner testified that he went to work at RWMC in Scottsbluff, Nebraska in 2012. Tr. 5.23 to 6.1. It was around that time that he received a letter from his employer that his blood work did not show any antibodies to hepatitis B and he would be required to take the vaccine. Tr. 5.12 to 5.20.

Petitioner stated that after receiving the first hepatitis B vaccine in 2012, he developed a nonspecific rash on his chest that was not itchy or painful; the rash went away on its own.[12] He attributed the rash to climate/location change and did not seek any medical intervention. Tr. 6.2 to 6.14; 47.11 to 47.16. After the second vaccination, he developed a lesion on his left shoulder and asked Dr. Massey to do a biopsy because it was on a sun-exposed area and he was concerned for basal cell carcinoma. Tr. 6.15 to 7.1. However, he stated that the redness disappeared the following week, so he never went for the biopsy. Tr. 7.2 to 7.5. Petitioner testified that there would not be any medical records documenting the rash on his chest or the lesions on his shoulder, though he may have showed the rash to his wife. Tr. 48.2 to 48.18.

In early April of 2015, petitioner was informed that he needed a third hepatitis B vaccine because his blood work failed to show that he had developed antibodies from the first two hepatitis B vaccines.[13] Tr. 7.6 to 7.17. He recalled arguing with the nurse about receiving a third vaccine, but was told that it was mandatory. Tr. 7.14 to 7.17. When asked on cross examination if there would be any documentation regarding his resistance to taking the third vaccination, he indicated he would not know if it was documented by the nurse. Tr. 48.19 to 49.23.

Petitioner testified that approximately a month after the third vaccination, he noticed scabbing with a rash on the top of his head in the area where he wore his surgical headlamp. Tr. 8.10 to 8.17. He explained that he wears a headlamp that is mounted on his forehead by a band during surgery for 6 to 7 hours at a time; the rash started under the headlamp. He stated that he would scratch at his head and pull off the scabs, but thought it was an allergic reaction to the plastic in the hardware. Tr. 8.17 to 8.23; 72.11 to 72.21. Petitioner stated that at that same time, he noticed that he had bleeding when he brushed his teeth and assumed it was time for dental cleaning. He was also having nose bleeds. Tr. 8.25 to 9.12. He also noted "a little sore on the bottom of my nose that looked like a pimple" and "some inflammatory changes on the eyelid that looked like a stye." Tr. 11.2 to 11.4.

[12] Petitioner stated in his affidavit that he developed the rash on his chest after receiving the second hepatitis B vaccine. Pet. Ex. 6 at 1.

[13] Petitioner's medical records reflect that on September 4, 2014, his bloodwork was negative for antibodies to hepatitis B. Pet. Ex. 1 at 1. However, there are no medical records to support any other instance of petitioner testing negative for hepatitis B antibodies.

On cross examination, Dr. Henley was questioned about his April 14, 2015 visit to the PCP for prostate issues and swelling of his legs; he was asked why he did not mention the bleeding gums or skin lesions. Pet. Ex. 2 at 1-3; Tr. 51.7 to 51.10. Petitioner explained that he was concerned about the ankles swelling, because it could be an indication of a heart related issue, and because he was not feeling well. Tr. 50.6 to 51.6. He did not recall his gums bleeding at that time, but since this was an internist visit, he probably would not talk about things not pertinent to the specific issue he was there for. Tr. 51.11 to 51.14. Similarly, he did not have any painful lesions at that time, nor to his recollection was he experiencing nose bleeds. Tr. 51.17 to 52.5.

I asked Dr. Henley if he recalled having the stye on April 14, 2015. He responded that it was not visible or noticeable at that time, and so minor at first it was easy to ignore but he first noticed it sometime in May. Tr. 71.10 to 72.9. I asked when he first noticed the lesion on his nose, to which he responded that it was around the same time as the eye and the scalp. Tr. 74.14 to 74.18.

Petitioner was questioned the dental record for June 23, 2015, which states "Gums are tender and bleeding on the right side, top and bottom." Pet. Ex. 9; Tr. 21.17 to 21.19. Petitioner explained that he was getting bleeding when he brushed his teeth, and had tenderness up on the right side of his mouth that had been going on for a while. He thought it was his own negligence in dental care, so he increased flossing and used better cleaning habits for several weeks, but his gums continued to bleed; he then made an appointment with the dentist. Tr. 22.7 to 22.11; 24.5 to 24.9; 55.16 to 55.18; 56.3 to 56.15. He was not initially concerned with the bleeding and thought he just needed a cleaning, but became more concerned "after I scheduled the appointment because I tried everything in the interim to make it better and it wasn't getting better. As a matter of fact it was getting worse…" Tr. 63.15 to 63.21.

While conceding that he had inflammation and gingivitis in past, "…this was different. It was more localized to the right side: it was more painful; and the bleeding did not resolve with improved dental hygiene." Tr. 55.25 to 56.2; 58.11 to 58.22. Then, there was the "abscess" on the right side, and an emergency visit for a root canal due to extreme pain. Tr. 44.12 to 45.2; 64.23 to 65.3. "…later on…when the tooth problem was over, I was able to really see a specific lesion on the right side…with a flashlight." Tr. 75.1 to 75.18; 76.12 to 76.17.

On cross examination, petitioner agreed that his first dental visit was on June 23, 2015, for the bleeding gums he claimed began after the April vaccination. He explained that because of his work schedule, coordinating when he would be in Scottsbluff with the dentist's availability would result in an appointment a month later. Tr. 10.8 to 10.14; 24.9 to 24.11; 55.10 to 55.15; 62.20 to 63.11.

Petitioner testified that around the same time as the dental issues, he had a surgical case with Dr. Blomstedt, who focuses on dermatology. Tr. 11.5 to 11.7. He and Dr. Blomstedt do dermatological cancer cases together; Dr. Blomstedt removes the cancer, and petitioner reconstructs the area. Tr. 11.8 to 11.11. Petitioner stated that after a surgery they had together, he stopped by Dr. Blomstedt's office and asked him to take a look at his head. Tr. 12.6 to 12.10. Dr. Blomstedt thought it looked like a rash and gave petitioner some samples of steroid and antibiotic creams to try. Tr. 11.14 to 11.18; 16.16 to 16.21. Dr. Henley recalled using the samples from Dr. Blomstedt on and off for about a month, but added that he may have used bacitracin on his own before that. Tr. 77.8 to 77.16.

Petitioner stated that the bleeding gums, nosebleeds, and scalp lesions were all happening at the same time, but he did not connect the dental issues with the skin issues on his scalp, nose and eye. Tr. 24.11 to 24.15; 56.16 to 56.24; 57.15. He further stated that he assumed that the antibiotics prescribed by the dentist would work on the other inflammatory skin lesions. He stated that a normal stye would have gotten better with antibiotics, but his eye did not; that was when he told Dr. Blomstedt that he needed biopsies done. Tr. 65.4 to 65.17.

On cross examination, petitioner was asked if there were any doctor visits in May of 2015. Petitioner responded that he did not have any official medical appointments, but knew that he had connected with Dr. Blomstedt after hours as a colleague. Tr. 15.14 to 15.25; 52.10 to 52.18. Petitioner further stated that, because Dr. Blomstedt gave him samples of medications to try, there would not be any pharmacy records. Tr. 52.22, 54.5 to 55.12.

Petitioner noted that he experienced a gradual escalation of symptoms, then increasing pain. The point where irritation escalated to pain is blurry. By the time he realized that he needed a biopsy, the scalp irritation had become lesions. Tr. 77.23 to 77.25; 78.4 to 78.11; 18.16 to 18.22. The lesion on his eye looked like a stye, but kept getting worse even with compresses. "[W]hen the eye lesion was going on for about six weeks, I finally broke down and I had an eye appointment." Tr. 18.22 to 18.25, 19.15 to 19.18.

Petitioner conceded that his first formal visit with Dr. Blomstedt was August 24, 2015; because he wanted biopsies, a formal visit had to be scheduled. At that visit, Dr. Blomstedt wrote "chronic rash on his forehead." Pet. Ex. 3 at 1. Petitioner explained that it was "chronic" because he had seen Dr. Blomstedt for it before, informally. The record also noted lesions on the right lower eyelid and the right side of his nose. Pet. Ex. 3 at 1; Tr. 17.16 to 17.24. Dr. Blomstedt performed biopsies of the lesions on petitioner's nose and scalp. Tr. 19.19 to 20.20. Both of the biopsies came back with a preliminary diagnosis of suspected autoimmune disorder. Tr. 20.23 to 21.4.

Petitioner testified that around the same time as the biopsies were done on his scalp and nose, he saw an ophthalmologist for his eye. When the ointment and compresses did not work, he was sent to an eyelid specialist, who did a biopsy of the eye lesion. Tr. 27.21 to 28.6. That biopsy came back consistent for pemphigus as well. Tr. 29.16 to 29.23. Petitioner stated that at that point he had three biopsies from three different sites, all with the same result. Tr. 29.4 to Tr. 29.5.

Petitioner explained that pemphigus vulgaris is a rare but serious disorder. If left untreated, it has a 70% mortality rate; treatment reduces the mortality rate to 10%, but immunosuppression is a side effect of the treatment. Tr. 25.12 to 25.16; 26.8 to 26.14; Pet. Ex. 3 at 3. Petitioner stated that he has antibodies for both pemphigus vulgaris and pemphigus foliaceus. Tr. 31.10 to 31.14.

Petitioner stated that he then went on a quest to find a specialist; since there was no one at RWMC who had experience with pemphigus, he went to the University of Colorado, which took several weeks. Tr. 25.17 to 25.22.

On September 24, 2015, he presented to Drs. Norris and Caldwell at the University of Colorado. Tr. 26.19 to 26.25. Having worked at a university in New Haven, petitioner explained

that the initial work up is done by the resident, and all of the computer entries and demands of the system are done by the residents. Tr. 27.1 to 27.5. Dr. Norris was the attending who then saw him in the presence of the residents, as it is a teaching as well as a treatment situation. Tr. 27.5 to 27.8.

The initial record at the University of Colorado, dated September 24, 2015, states "67 year old Ashkenazi Jewish Caucasian male who comes to the clinic for the first time for evaluation of pruritic and painful rash of two month duration involving scalp, face and chest." Pet. Ex. 4 at 3; Tr. 31.23 to 32.21. Petitioner explained that in the beginning the rash on his head was not painful and could be ignored, but over time, the rash developed into lesions, and became so painful that it hurt to take a shower and could no longer be ignored. Tr. 32.22 to 33.6. He described his conversation with Drs. Norris and Caldwell as "fairly loose." He recalled stating that some months ago, he had a final hepatitis B booster shot and then developed some rashes that were now painful. Tr. 33.19 to 33.23; 34.24 to 35.1. Petitioner explained that thinking back, it all started after the booster shot. Tr. 34.9 to 34.11.

The record of his visit to the University of Colorado on October 22, 2015 states "[A]fter receiving the third round in 7/2015, he noted diffuse onset of erosion on the scalp, face and chest." Pet. Ex. 4 at 23. Petitioner stated that on this visit, he saw Dr. Pearson, another resident. He explained to Dr. Pearson that the rash/lesions started with the scalp, nose, eye, and later, the remainder of the body. Tr. 37.22 to 38.4. Petitioner was asked where Dr. Pearson got the July 2015 date for the third vaccine; he replied that, when asked how long ago he had received the third hepatitis B vaccine, he had stated that it was several months or a few months ago. Tr. 38.25 to 39.18.

IV. Discussion and Findings of Fact

Respondent requested a fact hearing due to a lack of medical records for over a two month period following petitioner's hepatitis B vaccine on April 3, 2015. The lack of medical records following the April 3, 2015 hepatitis B vaccine is not a death knell to petitioner's claim. Petitioner's lifestyle and profession lend itself to an understandable and convincing explanation for the gap in time between his vaccination and his first formal doctor's visit, which was on June 23, 2015. Based upon petitioner's testimony, the onset of rashes/lesions and dental issues was within weeks of his vaccination. Moreover, when petitioner finally saw the respective specialists in the summer of 2015, he consistently told them that the rashes/lesions and dental issues began within weeks of his hepatitis B vaccination.

Considering petitioner's work and travel schedule, time can understandably have eluded him. It is not surprising that petitioner, as a physician, would attempt self- treatment for a minor skin condition and routine dental issues. As petitioner works in a multi-disciplinary medical setting, his access to medical personnel or colleagues for informal consultation for what appeared to be a minor skin irritation after weeks of failed self-treatment is an expected and acceptable perk of his profession.

Petitioner's description of his condition between April 3, 2013 and in the months that followed is that of a slowly developing and insidious disease, which initially appeared with random and seemingly unrelated but benign symptoms. It was not until months later that the severity of

the disease became evident. The supporting medical records further reflect that petitioner's lesions were constant into September of 2015, but then became dramatically more widespread, with lesions to his body, eyes and both sides of the inside of his mouth, even though by that time he was in active treatment with oral steroids, Rituximab infusions and Dapsone.

Only after his diagnoses, was petitioner able to reflect upon the months following the third hepatitis B vaccination and realize that the rash on his head, stye, lesion on his nose, painful, bleeding gums and the abscess inside mouth were all related systemic symptoms of pemphigus vulgaris, a serious but rare autoimmune disease. Accepting the history that petitioner provided to the specialists as accurate, petitioner suffered a rash on his chest after the first hepatitis B vaccine which went away on its own, and then suffered a reddened lesion on his left shoulder, for which he consulted a colleague about performing a biopsy, but it too resolved on its own. The facts in this case provide strong proof of causation in fact from rechallenge, sometimes called challenge-rechallenge. *See Larive v. Sec'y of HHS*, No. 99-429V, 2004 WL 1212142 (Fed. Cl. Spec. Mstr. May 12, 2004). Furthermore, several of petitioner's doctors noted in the medical records that the hepatitis B vaccine was the cause of petitioner's pemphigus. Under section 300aa-13(a)(1), petitioner has sufficient evidence to support a prima facie case of cause in fact.

V. Conclusion

Consistent with the foregoing, petitioner is ordered to provide a settlement demand to respondent within 90 days of the issuance of this ruling.

The following is therefore ORDERED:

By no later than Wednesday, June 7, 2017, petitioner should provide a settlement demand to respondent.

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master